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10/507,932	01/09/2006	Mark G. Erlander	14255-052US1	7099

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,932	ERLANDER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/05; 1/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Claims 1-38 are pending and considered for examination in this office action.

Priority

2. This application filed on January 9, 2006 is a 371 of PCT/US03/07785 filed on 3/14/03 which claims benefit of US provisional application 60/364,492 filed on 03/15/2002.

Information Disclosure Statement

3. The Information Disclosure Statement filed on January 18, 2005 and January 17, 2006 have been considered.

Objection to the abstract

4. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because the abstract submitted (abstract of WO 03/079667 A1) is not in accordance to the instant specification it does not contain a concise statement to which the invention pertains. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 1, 3-7, 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al. (US 6,794,138).

Cao et al. teach a method of claim 1, 9-10, for producing amplified RNA (aRNA) comprising

(a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA (see at least col. 7, line 60-67, col. 7, line 1-4, col. 20, line 35-43, col. 10, line 30-42);

(b) treating the reverse transcription product with RNAse H enzymatic activity (see at least col8, line 22-27, col. 10, line 43-49, col. 20, line 45);

(c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA (see col. 20, line 46-48, col. 8, line 4-11);

(d) producing amplified RNA from the eluted double stranded cDNA by invitro transcription using a DNA dependent RNA polymerase which initiates transcription from the primer of said promoter-primer complex (see col. 8, line 11-17, 35-44, col. 16, line 8-9);

wherein the product produced after c) and before d), after d) or both, is purified by contacting said product with a solid phase which binds nucleic acids followed by eluting bound nucleic acids from the solid phase in an volume less than 50ul (see col. 16, line 8-22, indicating that the product produced after c) and after d) are purified, especially the product produced after d) is contacted with solid phase (column) and eluted in 4ul of volume).

With regard to claim 3-4, Cao et al. teach that said RNA template is mRNA or cellular mRNA (see at least col. 7, line 60-61, col. col. 9, line 65-67, col. 10, line 1-3).

With regard to claim 5-6, Cao et al. teach that the promoter-primer complex comprises oligo or poly dT sequence of at least about eight dT in length as the primer (see col. 7, line 60-65, col. 15, line 55-57).

With regard to claim 7, Cao et al. teach that the random primers are six nucleotides in length (see at least col. 15, line 15-16).

With regard to claim 11, Cao et al. teach that the promoter-primer complex comprises a T7 promoter sequence (see col. 7, line 60-65).

With regard to claim 12-14, Cao et al. teach that the solid phase comprises silica particle filter (Qiagen column) see col. 16, line 17-22). Accordingly Cao et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 2, 20-23, 25-31, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. (US 6,794,138) in view of Baugh et al. (Nucleic Acids Res., Vol. 29, No. 5e29 1-9, 2001).

Cao et al. teach a method of claim 2, producing amplified RNA as discussed above in section 5. With regard to claim 21, 38, Cao et al. also teach reamplification of amplified RNA using random primers and promoter primer and producing re-amplified RNA (see col.20, line 50-62, col. 16, line 23-61). With regard to claims 22, 27, Cao et al. teach that the promoter-primer comprises T7, T3 and Sp6 promoter regions (see col. 10, line 56-65).

However, Cao et al did not teach reaction time for synthesis of first, second strand cDNA and aRNA in 45 minutes or less.

Baugh et al. teach a method of claim 2, 20, 38, for producing amplified RNA (aRNA) comprising

(a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA (see page e29, 2, col. 1, paragraph 2, col. 2, paragraph1);

(b) treating the reverse transcription product with RNAse H enzymatic activity (see page e29 2, col. 2, paragraph1);

(c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA (see page e29 2, col. 2, paragraph1);

(d) producing amplified RNA from the eluted double stranded cDNA by invitro transcription using a DNA dependent RNA polymerase which initiates transcription from the primer of said promoter-primer complex (see e29 2, col. 2, paragraph1);

wherein the product produced after c), after d) or both, is purified by contacting said product with a solid phase which binds nucleic acids followed by eluting bound nucleic acids from the solid phase (see e29 2, col.1, paragraph 2, col. 2, line 6-9, paragraph 2 indicating that the product produced after c) and d) are purified, especially the product produced after d) is contacted with solid phase (paramagnetic bead).

With regard to claim 2, 20, Baugh et al. teach said first and second strand cDNA synthesis is carried out in a reaction time less than 45 minutes (see page e29 2, col. 2, paragraph 1, indicating 40 min at 42^0 C and 10 min at 50^0 C).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of producing amplified RNA as disclosed by Cao et al. in a manner as taught by Baugh et al. with a step of reducing time for synthesis of aRNA for the purpose of developing a rapid and quick method for producing aRNA. One skilled in the art would be motivated to combine the method as disclosed by Cao et al. with the method of Baugh et al. because an ordinary artisan would have a reasonable expectation of success that the combination would result in less process time and cost-effective method because Baugh et al. explicitly taught that the process time can be shorted depending on the incubation temperatures (see page e29 2, col. 2, paragraph 1) and such modification of the method would be obvious over the cited prior art.

B. Claims 15-19, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Cao et al. (US 6,794,138) in view of Baugh et al. (Nucleic Acids Res., Vol. 29, No. 5e29 1-9, 2001) as applied to claims 2, 20-23, 25-31, 38 above, and further in view of Smith et al. (USPN. 6,027,945).

Cao et al. in view of Baugh et al. teach a method of producing amplified RNA as discussed above in section 6A.

However, neither Cao et al. nor Baugh et al. teach that the solid support comprising silica particles or diatomaceous earth, wetting capacity, elution by centrifugation.

Smith et al. teach a method of isolating biological target materials (nucleic acids) using a silica magnetic solid particles, wetting capacity equal to elution volume and elution by centrifugation wherein Smith et al. teach that the method comprises providing a solid phase (silica particles) and combining the solid phase with the biological material and isolating the target-solid phase complex and recovering the biological material from the solid phase (see col. 5, line 1-30).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Cao et al. in view of Baugh et al. with a step of purifying the nucleic acid as taught by Smith et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to combine the teaching of Cao et al. in view of Baugh et al. with the step of isolating the nucleic acids as taught by Smith et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in purifying nucleic acids and improve the quality of the amplified nucleic acid because Smith et al. explicitly taught the silica particle packed column to purify nucleic acids for

biological analysis (see col. 5, line 1-30) and such modification of the method would be considered as obvious over cited prior art.

C. Claims 8, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. (US 6,794,138) in view of Baugh et al. (Nucleic Acids Res., Vol. 29, No. 5e29 1-9, 2001) as applied to claims 2, 20-23, 25-31, 38 above, and further in view of Gerdes et al. (US 6,872,527).

Cao et al. in view of Baugh et al. teach a method of producing amplified RNA as discussed above in section 6A.

However, neither Cao et al. nor Baugh et al. teach random primers of nine nucleotides or longer.

Gerdes et al. teach a method for genome wide amplification wherein the method utilizes 9-mer random primers to boost the amplification of entire or large fraction of the genome (see col. 26, line 23-64).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Cao et al. in view of Baugh et al. with a step of random primers of nine nucleotides or longer in length as taught by Gerdes et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to combine the teaching of Cao et al. in view of Baugh et al. with the step of random primers of nine nucleotides as taught by Gerdes et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in amplifying a large fraction or entire nucleic acid of interest because Gerdes et al. explicitly taught the use of 9-mer random primers provide amplification of entire or a large fraction of the nucleic acid (see col. 26, line 56-64) and such modification of the

method would be considered as obvious over cited prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru 6/11/07
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